

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Group Art Unit 1614

In re Patent Application of:

Richard B. Mazess et al.

Filed: June 27, 2003

Application No.: 10/608,480

Confirmation No.: 7844

Examiner: Not Assigned

Entitled: MULTI-USE VESSELS FOR

VITAMIN D FORMULATIONS

I, Sally J. Sorensen, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

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January 7,

7, 2004

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 CFR §1.97(b)(3)

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

The Examiner's attention is directed to the references which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B. Copies of the references are attached. Citation of these references is respectfully requested.

In accordance with 37 CFR 1.97(b)(3) these references are provided before the mailing of a first Office Action on the merits.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted

Jefffy D. Peterson

Reg. No. 49,038

File No. 017620-9373

Michael Best & Friedrich LLP One South Pinckney Street P. O. Box 1806 Madison, W1 53701-1806 (608) 257-3501

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the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known stitute of form 1449/PTO 10/608,480 **Application Number** INFORMATION DISCLOSURE STATEMENT BY Filing Date June 27, 2003 **APPLICANT** First Name Inventor Richard B. Mazess 1614 Group Art Unit **Examiner Name** Unknown (use as many sheets as necessary) Attorney Docket Number 017620-9373 of Sheet

U.S. PATENT DOCUMENTS					
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	
		2,383,446	Calcott et al.	06/04/41	
	AA		DeLuca et al.	10/10/72	
	AB	3,697,559	DeLuca et al.	06/26/73	
	AC	3,741,996			
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	AR	4,689,180	DeLuca et al.	08/25/87	
	AS	4,698,328	Neer et al.	10/06/87	

Examiner	Date	
Signature	Considered	

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INFORMATION DISCLOSURE STATEMENT BY First Name Inventor Richard B. Mazess Group Art Unit 1614 Unknown Examiner Name (use as many sheets as necessary) 017620-9373 Attorney Docket Number of Sheet 2

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
AT	4,717,721	DeLuca et al.	01/25/88
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First Name Inventor Richard B. Mazess

Group Art Unit 1614

Attorney Docket Number

Examiner Name

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_		U.S.	PATENT DOCUMENTS	
Examiner Initials		U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document
	BN	5,554,386	Groman et al.	09/10/96
	во	5,597,575	Breitbarth	01/28/97
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	BS	5,661,025	Szoka, Jr. et al.	08/26/97
	вт	5,691,328	Peterson et al.	11/25/97
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	BX	6,537,982	Bishop et al.	03/25/03

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	BY	Belgium	877 356	Wisconsin Alumni Research Foundation	10/15/79		
	BZ	Japan	5320127	Nisshin Flour Milling Co.	09/29/93		
	CA	Japan	6025039	Kurary Co. Ltd.	02/01/94		
	СВ	Japan	62000033	General Hospital	10/15/86		
	СС	EP	0197514	General Hospital	10/15/86		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

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First Named Inventor	Richard B. Mazess	
Group Art Unit	1614	
Examiner Name	Unknown	
Attorney Docket Number	017620-9373	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.					
	A1: T 4 1 4 7 14 (1000) 04 401 00					

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СТ	Barton, D. et al., "Synthetic Uses of Steroidal Ring & Diene Protection: 22,23-Dihydroergosterol," JCS Perkin I, (1976) pp. 821-826.
CU	Beer, et al., "A Phase I Trial of Pulse Calcitriol in Patients with Refractory Malignancies," Cancer, (June 15, 2001) 91:12:2431-2439.
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. CW	Beer, T. et al., "Weekly High-Dose Calcitriol and Docetaxel in Metastatic Androgen-Independent Prostate Cancer," <i>Journal of Clinical Oncology</i> , (Jan. 2003) 21:1:123-128.
CX	Blazsek, I. et al. "Combined Differentiation Therapy in Myelodysplastic Syndrome with Retinoid Acid, 1α,25 Dihydroxyvitamin D ₃ , and Prednisone," 16:4:259-264 (Abstract).
CY	Brautbar, N. "Osteoporosis: Is 1,25-(OH)2D3 of Value in Treatment?" Nephron (1986) 44:161-166.
CZ	Braunwald, E. et al., <i>Harrison's Principles of Internal Medicine:</i> Part Eleven, "Disorders of Bone and Mineral Metabolism," Chapter 335, McGraw-Hill, New York, (1987) pp. 1860-1865.
DA	Brown, J.P. et al., "Serum Bone Gala-Protein: A Specific Marker for Bone Formation in Postmenopausal Osteoporosis," <i>Lancet</i> , (1984) 1:1091-1093.
DB	Caniggia, A. et al., "Effect of a Long-Term Treatment with 1,25-Dihydroxyvitamin D ₃ on Osteocalcin in Postmenopausal Osteoporosis," <i>Cacified Tissue Int.</i> , (1986) 38:328-332.
DC	Christiansen, C. et al., "Prevention of Early Postmenopausal Bone Loss: Controlled 2-Year Study in 315 Normal Females," <i>Europ J Clin Inves.</i> , (1980) 10:273-279.
DD	Christiansen, C. et al., Eur. J. Clin. Invest., (1981) 11:305-309.
DE	Crump, D.R. et al., "(22S)-Hydroxyvitamin D ₄ ," <i>J.C.S. Perkins Trans. I</i> , (1973) pp. 2731-2733.
DF	Cho, Y.L. et al., "Combined Effects of 1,25-Dihydroxyvitamin D ₃ and Platinum Drugs on the Growth of MCF-7 Cells," <i>Cancer Research</i> , (June 1991) 51:2848-2853.
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DH	DeLuca et al., "Synthesis, Biological Activity, and Metabolism of 22,23-3H-Vitamin D ₄ ," Arch. Biochem, Biophys., (1968) 124:122-128.

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				First Name Inventor	Richard B. Mazess
				Group Art Unit	1614
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•	Sheet 4	of	1	Attorney Docket Number	017620-9373

	U.S. PATENT DOCUMENTS					
Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document			

			FO	OREIGN PATENT DOCUMENT	S		
Examiner Initials		Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	CD	EP	0390097	Nisshin Flour Milling Co.	10/03/90		
	CE	EP	0562497	Nisshin Flour Milling Co.	09/29/93		
	CF	EP	0503630	Kuraray Co. Ltd.	09/16/92		
	CG	EP	0664287	Duphar International	07/26/95		
	СН	PCT	WO 84/04527	Wisconsin Alumni Research Foundation	11/22/84		
	CI	PCT	WO 87/00834	Leo Pharmaceutical Products, Ltd.	02/12/87		
	Cì	PCT	WO 90/10620	Wisconsin Alumni Research Foundation	09/20/90		
	СК	PCT	WO 92/05130	Lunar Corporation	04/02/92		
	CL	PCT	WO 92/12165	Lunar Corporation	07/23/92		
	СМ	PCT	WO 92/21355	Procter & Gamble	12/10/92		
	CN	PCT	WO 93/07883	ISIS Pharmaceuticals	04/29/93		
	СО	PCT	WO 93/14763	Lunar Corporation	08/05/93	-	
	СР	PCT	WO 94/16711	Lunar Corporation	08/04/94		
	CQ	PCT	WO 96/40153	Bone Care International	12/19/96		
	CR	PCT	WO 99/49870	Oregon Health Sciences	10/07/99		

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Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Complete ij Known

10/608,480

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June 27, 2003

Richard B. Mazess

Group Art Unit

1614

Examiner Name

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Attorney Docket Number

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Signature	Considered	

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First Named Inventor Richard B Mazess

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(use as many sheets as necessary)				Examiner Name	Unknown		
Sheet	3	of	6	Attorney Docket Number	017620-9373		
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
	DW	Jensen, G.F. et al., "Treatment of Post Menopausal Osteoporosis. A Controlled Therapeutic Trial Comparing Oestrogen/Gestagen, 1,25-Dihydroxy-Vitamin D ₃ and Calcium," <i>Clin. Endocrinol.</i> , (1982) 16:515-524.
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	DY	Jones, G. et al., "Isolation and Identification of 1,25-Dihydroxyvitamin D ₂ ," <i>Biochemistry</i> , (1975) 14:1250-1256.
	DZ	Kanis, J.A. et al., "Guidelines for Clinical Trials in Osteoporosis, A Position Paper of the European Foundation for Osteoporosis," <i>Osteoporosis Int.</i> , (1991) 1:182-188.
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	ED	Lam, H.Y. et al., Science, (1974) 486:1038-1040.
	EE	Londowski, J.M. et al., "Biological Activity of the C-1, C-3, C-25, β-D-Glucopyranosides of 1,25-Dihydroxyvitamin D ₃ ¹ ," J. Pharmacology Expr. Ther., (1986) 237:3:837-840.
	EF	Majewski, et al., "Inhibition of Tumor Cell-Induced Angiogenisis by Retinoids, 1,25-Dihydroxyvitamin D ₃ and their Combination," Cancer Letters, (1993) 75:35-39.
	EG	Martin and DeLuca, "Calcium Transport," Am. J. Physiol., 216:1352-1359.
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	EI	McDonald, F.G., "The Multiple Nature of Vitamin D," J. Biol. Chem. 114, (1936) 1xv.
	EJ	Merck Index, S. Budavari (ed.), 11th ed., Merck & Co., Rahway, N.J. (1989) pp. 1579, #9930
	EK	Miller et al., "The Human Prostatic Carcinoma Cell Line LNCaP Expresses Biologically Active, Specific Receptors for $1\alpha,25$ -Dihydroxyvitamin D_3^1 ," Cancer Res., (1992) 52:515-520.

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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
	EL	Moffatt, K. et al., "1α,25-Dihydroxyvitamin D ₃ and Platinum Drugs Act Synergistically to Inhibit the Growth of Prostate Cancer Cell Lines," <i>Clinical Cancer Research</i> , (March 1999) 5:695-703.
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	EO	Orimo, H. et al., "Reduced Occurrence of Vertebral Crush Fractures in Senile Osteoporosis Treated with 1α(OH)-Vitamin D ₃ ," <i>Bone and Mineral</i> , (1987) 3:47-52.
•	EP	Ott, S.M. and C.H. Chesnut, Annals of Int. Med., (1989) 110:267-274.
	EQ	Paaren et al., "Direct C(1) Hydroxylation of Vitamin D ₃ and Related Compounds," <i>J. Org. Chem.</i> , (1980) 45:3253.
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Cubetitute for	orm 1449B/PTO			Complete if Known		
THE THE PARTY OF T	0111114478/1110			Application Number	10/608,480	
INFOR	MATION	N DISCL	OSURE	Filing Date	June 27, 2003	
STATE	EMENT B	Y APPL	ICANT	First Named Inventor	Richard B. Mazess	
~				Group Art Unit	1614	
	(use as many she	ets as necessary))	Examiner Name	Unknown	
Sheet	5	of	6	Attorney Docket Number	017620-9373	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
	FA	Sjoden et al., "Effects of 1 OHD ₂ on Bone Tissue," <i>Acta. Endocrinol.</i> (Copenh.) (Aug. 1984) 16:4:564-568.
	FB	Sjoden, G. et al., "Antirachitic Activity of 1α-Hydroxyergocalciferol and 1α-Hydroxycholecalciferol in Rats," J. Nutr., (1984) 114:2043-2046.
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	FD	Skowronski et al., "Actions Of Vitamin D ₃ Analogs on Human Prostrate Cancer Cell Lines: Comparison with 1,25-Dihydroxyvitamin D ₃ ," <i>Endocrinology</i> , (1995) 136:20-26.
,	FE	Skowronski et al., "Vitamin D and Prostate Cancer: 1,25 Dihydroxyvitamin D ₃ Receptors and Actions in Human Prostate Cancer Cell Lines," <i>Endocrinology</i> , (1993) 132:1952-1960.
	FF	Slapak, C. et al., "Treatment of Acute Myeloid Leukemia in the Elderly with Low-Dose Cytarabine, Hydroxyurea, and Calcitriol," <i>Amer. J. Hematology</i> , (1992) 41:178-183.
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	FH	Song, X.D. et al., "Bryostatin-1 and 1α,25-Dihydroxyvitamin D ₃ Synergistically Stimulate the Differentiation of NB4 Acute Promyelocytic Leukemia Cells," <i>Leukemia</i> , (1999) 13:275-281.
	FI	Sorensen, O.H. et al., Clin. Endocrinol., (1977) 7:169S-175S.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

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	Complete if Known	
Application Number	10/608,480	
Filing Date	June 27, 2003	
First Named Inventor	Richard B. Mazess	<u> </u>
Group Art Unit	1614	
Examiner Name	Unknown	
Attorney Docket Number	017620-9373	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
	FP	Tanaka, Y. et al., <i>Endocrinology</i> (1973) 92:417-422.
	FQ	Torres, R. et al., "Etoposide Stimulates 1,25-Dihydroxyvitamin D ₃ Differentiation Activity, Hormone Binding and Hormone Receptor Expression in HL-60 Human Promyelocytic Cells, <i>Molecular and Cellular Biochemistry</i> , (2000) 208:157-162.
	FR	Tsuji, M. et al., "Synthesis of 22,23-Dihydro-1α,25-Dihydroxyvitamin D ₂ and its 24R-Epimer, New Vitamin D ₂ Derivatives," <i>Bull. Chem. Soc. Jpn.</i> , (1990) 63:8:2233-2238.
	FS	Wang, Q. et al., "1,25-Dihydroxyvitamin D ₃ and All-trans-Retinoic Acid Sensitize Breast Cancer Cells to Chemotherapy-induced Cell Death," Cancer Research, (April 2000) 60:2040-2048.
9	FT	Wang, X. et al., "Inhibition of p38 MAP Kinase Activity Up-Regulates Multiple MAP Kinase Pathways and Potentiates 1,25-Dihydroxyvitamin D ₃ -Induced Differentiation of Human Leukemia HL60 Cells," <i>Experimental Cell Research</i> , (2000) 258:425-437.
	FU	Wientroub, S. et al. "The Dichotomy in the Effects of 1,25 Dihydroxy Vitamin D ₃ and 24, 25 Dihydroxy Vitamin D ₃ on Bone Gamma-Carboxyglutamic Acid-Containing Protein in Serum and Bone in Vitamin D-Deficient Rats," <i>Calcif, Tissue Int.</i> , (1987) 40:166-172.
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	FW	Yu, W. et al., "Enhancement of 1,25- Dihydroxyvitamin D ₃ - Mediated Antitumor Activity with Dexamethasone," <i>J. National Cancer Inst.</i> , (January 1998) 90:2:134-141.
	FX	Zerwekh et al., "Short-Term 1,25-Dihydroxyvitamin D ₃ Administration Raises Serum Osteocalcin in Patients with Postmenopausal Osteoporosis," <i>J. Clin. Endocrinol. Metabol</i> , (1985) 60:615-617.

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